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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,041	12/26/2001	Luc Desnoyers	P3030R1C8	4333

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/036,041	Applicant(s) DESNOYERS ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26,36 and 38-51 is/are pending in the application.
- 4a) Of the above claim(s) 46-51 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45 is/are allowed.
- 6) ☒ Claim(s) 22-26,36 and 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-26,36 and 38-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/24/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's amendment filed on 24 May 2004 is acknowledged and entered. Following the amendment, claim 35 is canceled, claim 36 is amended, and the new claims 42-51 are added.

Newly submitted claims 46-51 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 46-51 encompass specific and non-overlapping nucleic acid fragments of SEQ ID NO:1, or nucleic acid fragments encoding small fragments of SEQ ID NO:2 (20 amino acids, for example). The encoded small amino acid fragments of the claims such as residues 45-78, 137-167, and 202-221 of SEQ ID NO:2 are unlikely to share the same biological property as that of SEQ ID NO:2. Further, due to the use of "comprising" language, it cannot even be said that the search of SEQ ID NO:1 and nucleic acids encoding SEQ ID NO:2 would reveal art pertaining to, for instance, nucleic acid encoding a polypeptide *comprising* amino acids 202-221 of SEQ ID NO:2, as it could be found embedded in a completely different nucleic acid molecule encoding a polypeptide distinct from that of SEQ ID NO:2. Accordingly, non-coextensive searches are required for each fragment. Additionally, the burden of search for the Office has increased with multiple sequences because of the rapid introduction of new sequences to public sequence databases.

Since applicant has received an action on the merits for the originally presented invention, a nucleic acid having SEQ ID NO:1 or encoding a polypeptide comprising an amino acid sequence of SEQ ID NO:2, and variants thereof, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46-51 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Currently, claims 22-26, 36 and 38-51 are pending, and claims 22-26, 36 and 38-45 are under consideration.

Inventorship

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In view of the papers filed on 24 May 2004, the inventorship in this nonprovisional application has been changed by the deletion of Dan L. Eaton, Audrey Goddard, Paul J. Godowski, Austin L. Gurney, James Pan, Timothy A. Stewart, Colin K. Watanabe and Zemin Zhang.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Declaration

The declaration filed on 24 May 2004 under 37 CFR 1.131 is sufficient to overcome the Piddington reference, US 6,521,233 B1. However, it is ineffective to overcome another Piddington reference, US 2003/0165530 (see the new rejection below under **Rejections Over Prior Art**).

The Piddington reference, US 2003/0165530, is a U.S. patent or a U.S. patent application publication that *claims* the rejected invention (see claims 22, 30, 31, and 43 of US 2003/0165530, for example). An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the patent may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

Withdrawal of Objections and Rejections:

All objections and rejections of claim 35 are moot as the applicant has canceled the claim.

The rejection of claims 22-26, 36 and 38-41 under 35 U.S.C. 102(e) as being anticipated by Piddington et al., US 6,521,233 B1, is withdrawn in view of applicant's declaration and argument.

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Formal Matters:

Claim 36 is objected to for the following informalities, appropriate correction is required for each item:

Part (a) and part (b) are identical; and the number (e) is missing in the claim.

Claims 43 and 44 are objected to as being dependent upon a canceled claim, claim 27. The applicant is required to rewrite the claims in independent form including all of the limitations of the base claim and any intervening claims, or to amend the claims to depend on a pending and elected claim.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is indefinite and confusing for the recitation of “washes at 42 °C in 0.2x SSC and 50% formamide at 55 °C” (lines 2-3 from the bottom). It is unclear how one wash can have two different temperatures, or separate washes with different temperatures are intended.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a nucleic acid of SEQ ID NO:1, and a nucleic acid encoding a polypeptide of SEQ ID NO:2, does not reasonably provide enablement for hybridization variants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to *make and use*

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the invention commensurate in scope with these claims, for the reasons set forth in the previous Office Actions mailed on 20 March 2003, and 25 February 2004, and for the reasons below.

Applicants argument filed on 24 May 2004 has been fully considered, but is not deemed persuasive for reasons below.

At page 9 of the response, the applicant argues that claim 36 has been amended to recite hybridization under specified stringent conditions, and thus, one of ordinary skill in the art can easily make and use the claimed hybridization variants without undue experimentation. This argument is not persuasive for the following reasons. Although the amended claim recites specified stringent conditions, the invention is still not commensurate in scope with the claim, which encompass the nucleic acid variants *hybridizing* under stringent conditions *to* a nucleic acid *sequence encoding* the polypeptide of SEQ ID NO:2, wherein the claimed nucleic acid does not have to encode a functional polypeptide of any kind, or does not have to encode a polypeptide at all. Given the possibility of codon degeneracy, the nucleic acid to which the claimed nucleic acid hybridizes could have merely 67% sequence homology to the disclosed nucleic acid of SEQ ID NO:1. Thus, the hybridization variant would have even lower or merely local sequence homology to such a "encoding" nucleic acid, and it may well be a molecule encoding a polypeptide distinct from SEQ ID NO:2 in structure and function, or an inactive polypeptide, or a molecule not encoding a polypeptide at all, as all it is required for the claimed nucleic acid is to hybridize to a nucleic acid sequence encoding the polypeptide of SEQ ID NO:2, and the claim does not even require the nucleic acid encoding a protein. Therefore, the recited condition would not guarantee for obtaining the claimed species encoding a variant of SEQ ID NO:2 with the same functional activity, and the specification provides no working example of any of such variants that would be within the limitations of the claims. As such, one of ordinary skill in the art would not know how to make a functional equivalent of SEQ ID NO:2, or how to use the hybridization variants encoding an inactive polypeptide or not encoding a polypeptide at all, and it would require undue experimentation in order to make and use the claimed invention in its full scope.

Claim 36 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous Office Actions mailed on 20 March 2003, and 25 February 2004, and for the reasons below.

Applicants argument filed on 24 May 2004 has been fully considered, but is not deemed persuasive for reasons below.

At page 10 of the response, the applicant argues, once again, that claim 36 has been amended to recite hybridization under specified stringent conditions, and thus, one of ordinary skill in the art would recognize that applicants possessed the claimed hybridization variants at the time the application was filed. This argument is not persuasive for the following reasons: the amended claim 36 merely requires the claimed nucleic acid hybridizing to, for example, a nucleic acid sequence encoding SEQ ID NO:2, which encompass any or all nucleic acids sharing some sequence homology enough to hybridize to the encoding nucleic acid (not necessarily SEQ ID NO:1), encoding a completely different polypeptide from SEQ ID NO:2, or not encoding a polypeptide at all. The specification does not disclose any of such hybridization variants meeting the limitations of the claims, one of skill in the art would have no basis to derive the claimed ranges of hybridization variants from the instant disclosure, and thus, would not be able to envision the detailed chemical structure of the encompassed, and to make such variants even though the level of skill and knowledge in the art is high.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 22-26, 36 and 38-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Piddington et al., US 2003/0165530 A1, for the same reasons of record set forth in the rejection of claims 22-26, 35, 36 and 38-41 under 35 U.S.C. 102(e) as being anticipated by Piddington et al., US6,521,233, made in the previous Office Action, paper No. 10, mailed on 21 August 2003,

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since US 2003/0165530 (pending) is a division of application 09/552,225, now US6,521,233, and has the same specification as that of the patent.

Additionally, some of claims of US 2003/0165530 *claim* the same invention as that in the present invention: claims 22, 30, 31, and 43 of US 2003/0165530, for example, claim the same invention as that of the present claims 24, and 42-44. As such, the declaration filed on 24 May 2004 under 37 CFR 1.131 is ineffective to overcome this reference for the reasons above.

Conclusion:

Claim 45 is allowable.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/20/04